

Appl. No. 10/076,967
Amdt. dated April 23, 2007
Amendment under 37 CFR 1.116 Expedited Procedure
Examining Group 1631

PATENT

REMARKS/ARGUMENTS

Reconsideration and allowance of the pending claims is respectfully requested in light of the remarks which follow. Claim 55 has been amended. Claim 75 has been amended to correct typographical errors. Support for the amendment of claim 55 may be found, for instance, in the specification at page 3, lines 23-24 and page 3, lines 28-32. No new matter has been added. Upon entry of this amendment, claims 55-66 and 68-81 will be pending for examination.

Claim rejections under 35 U.S.C. § 112, first paragraph - written description

Claims 55-66 and 68-81 stand rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement. In making this rejection, the Examiner has alleged that the recited limitation of "comparing the correlation" constitutes new matter. *See Office Action at page 3.* The Examiner notes that "[r]ather, the specification describes that the 'present invention provides methods for *correlating gene expression with protein expression*'. (Emphasis in original.) *See Office Action at page 3.* In order to expedite prosecution, Applicants have amended claim 1 to recite, in part, "A method of *correlating gene expression with protein expression* . . . thereby *correlating gene expression with protein expression* in two or more biological samples". (Emphasis added.) As acknowledged by the Examiner, this claim language finds support in the specification (for example, at page 3, lines 23-24); thus, this claim amendment obviates this ground for rejection. Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 112, first paragraph.

Claim rejections under 35 U.S.C. § 112, second paragraph - indefiniteness

Claims 55-66 and 68-81 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. To the extent that this rejection applies to the amended claims, Applicants respectfully traverse.

In making this rejection, the Examiner alleges that claim 55 is unclear because no actual "'correlation of gene and protein expression' has been performed within the steps of the claim", further alleging that "[t]he only correlation is that of a polypeptide that has a mass that correlates to the predicted mass". The Examiner then asks for clarification of whether "the correlation of gene and protein expression [is] indicated by a predicted mass that is the same as a

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mass generated in the protein profile". See Office Action at page 4. While Applicants respectfully submit that claim 55 was clear on this point prior to amendment, Applicants have amended claim 55 for the sake of clarity to recite, in part, "a polypeptide having a mass that is the same as the predicted mass of the encoded polypeptide . . . thereby correlating gene expression with protein expression in two or more biological samples". (Emphasis added.) Applicants submit that this amendment provides the clarification requested by the Examiner, thus obviating this ground for rejection.

The Examiner also alleges that claim 55 is unclear because "if the protein is present in only one sample, or in no samples (as is also recited in the claim, *i.e.*, "absence"), then the steps of the claim have only correlated expression in one sample (or none). There has not necessarily been a correlation of the one gene with the expression of a protein in two or more samples, as recited in the claim". See Office Action at page 5. In order to expedite prosecution, Applicants have amended step (g) of the claimed method to recite "determining the presence in each protein profile of a polypeptide having a mass that is the same as the predicted mass of the encoded polypeptide, thereby identifying at least one protein that is expressed from a corresponding mRNA in each biological sample . . .". Applicants submit that this amendment provides the clarification requested by the Examiner, thus obviating this ground for rejection.

The Examiner further alleges that claim 55 is unclear because "the steps have not correlated *any and all* genes to *any and all* expressed proteins, which is an embodiment encompassed by the language of the claims". (Emphasis added.) Additionally, the Examiner alleges that "the steps have not correlated expression of a *plurality* of genes to one or more proteins or one gene to a *plurality* of proteins, also encompassed by the language of the claims". (Emphasis added.) See Office Action at page 5. Accordingly, Applicants have amended claim 55 to recite "at least one mRNA" and "at least one protein". Applicants submit that these amendments provide clarification of the scope of the claim to cover "any and all" genes and proteins as well as a "plurality" of genes and proteins, as requested by the Examiner.

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In light of the foregoing, Applicants respectfully submit that the Examiner's concerns regarding claim clarity have been addressed. Accordingly, Applicants request withdrawn of the rejection under 35 U.S.C. § 112, second paragraph.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-472-5000.

Respectfully submitted,

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